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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
BAEK, BONG-SOOK	
ART UNIT	**PAPER NUMBER**
1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/557,196	RAJ ET AL.	
	Examiner	Art Unit	
	BONG-SOOK BAEK	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 December 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5,8-21,23-26 and 28-59* is/are pending in the application.

4a) Of the above claim(s) *1,5,8-13,15,17-21,23-26,28-31 and 34-59* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14, 16, and 32-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims withdrawn from consideration are 1, 5, 17-21, 23-26, and 42-44 with claims 8-13, 15, 28-31, 34-41, 45-46, and 59 .

Detailed action

Status of Claims

The amendment filed on December 22, 2008 is acknowledged. Claims 2-4, 6-7, 22, 27, and 60-71 have been canceled and claims 1, 5, 8-21, 23-26, and 28-59 are currently pending. Since claims 1, 5, 17-21, 23-26, 42-44, and 47-58 have been amended from use claims to method claims, those claims are no longer drawn to the elected invention (composition). Thus, the claims 1, 5, 17-21, 23-26, 42-44, and 47-58 with claims 8-13, 15, 28-31, 34-41, 45-46, and 59 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group or species, there being no allowable generic or linking claim. Claims 14, 16, and 32-33 are under examination in the instant office action.

Applicants' arguments, filed on December 22, 2008, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application. Responses are limited to Applicants' arguments relevant to either reiterated or newly applied rejections.

The following rejections are maintained for reasons of record and the followings.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 14, 16, and 32-33 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 5,025,019 (Issue Date: 6/18/1991).

The instant invention is drawn to a waking refreshed aid or a pharmaceutical formulation for enabling an individual to wake refreshed comprising triprolidine or a salt or hydrate thereof in combination with at least one further active pharmaceutical agent (elected species: ibuprofen) in association with a pharmaceutically acceptable carrier therefor and instructions for administration thereof at or just before the desired sleeping time. The instant invention is further drawn to the waking refreshed aid wherein the instructions for administration instruct a single dose of the triprolidine active ingredient of up to 20 mg, preferably between 0.01 and 20 mg prior to sleep time (claims 32-33).

US Patent 5,025,019 disclose a composition a non-steroidal anti-inflammatory drug including ibuprofen and in combination with at least one other active component selected from a decongestant, cough suppressant, expectorant or antihistamine including triprolidine for the relief of cough, cold and cold-like symptom (abstract and claim 1). US Patent 5,025,019 further teaches that the usual single dosage of triprolidine (HCL) is 1.25-2.5 mg (Table I, 3rd example), which falls within the claimed range in the instant claims 32-33 and the pharmaceutical composition will be administered in admixture with suitable pharmaceutical diluents, excipients or carriers (column 5, lines 57-66).

Since the instant invention is directed to a composition, an intended use, which is enabling an individual wake refreshed, does not have a patentable weight. In accordance with the patent statutes, an article or composition of matter, in order to patentable, must not only be useful and involve invention, but must also be new. If there is no novelty in an article or composition itself, then a patent cannot be properly granted on the article or composition, regardless of the use for which it is intended. The difficulty is not that there can never be invention in discovering a new process involving the use of an old article, but that the statutes make no provision for patenting of an article or composition which is not, in and of itself, new.

With regards to the instruction, the printed matter on a label or package insert of a kit or container does not lend patentable weight as a limitation of the claimed product, composition, or article of manufacture since there is no functional relationship between the label or package insert of a kit and the product, composition, or article of manufacture of a kit or container. See *In re Haller* 73 USPQ 403 (CCPA 1947), where it is held that application of printed matter to old article cannot render the article patentable. In the opinion text of In re Haller, it is stated that:

Whether the statement of intended use appears merely in the claim or in label on the product is immaterial so far as the question of patentability is concerned.

Also see *In re Venezia* 189 USPQ 49 (CCPA 1976), where kits are drawn to the structural attributes of interrelated component parts and not to activities that may or may not occur. Further, *In re Miller* 164 USPQ 46 (CCPA 1969) and *In re Gulak* (CAFC) 217 USPQ 401 relate to a mathematical device and to a measuring cup respectively as well as *In re Ngai*, 70 USPQ2d 1862 (CAFC 2004). In each of these cases, the printed matter is considered a patentable distinction because the function of the device depends upon the printed matter itself, which is a patentable distinction because the function of the device depends upon the printed matter itself, which is a part of the substrate; without the printed indicia or numbers, the substrates lose their function. Such is not the case with the instantly claimed articles or kits. The claimed articles of the kit remain fully functional absent the labeling or printed instructions for use. Thus the instructions for use included in a kit or article manufacture constitute an "intended use" for that kit or article of manufacture. Intended use does not impart patentable weight to a product. See MPEP 2111.02: Intended use recitations and other types of functional language cannot be entirely disregarded. However, in apparatus, article and composition claims, intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967); *In re Otto*, 312 F.2d 937, 938, 136 USPQ 458, 459 (CCPA 1963).

In the instant case, the kit claims are drawn to an old article or composition, which further comprises labeling instructions. The intended use, which is recited on the label or package of the insert, lacks a function relationship because the insert or label does not physically or chemically affect the chemical nature within the article of manufacture, and furthermore, the old article or old composition of the kit can still be used by the skilled artisan for other purposes. Therefore the old article or composition which are comprised with the claimed kit are unpatentable over the prior art, because they function equally effectively with or without the labeling, and accordingly no functional relationship exists between the instructions for use and the composition.

Thus the claims are addressed as being drawn to an article comprising an old composition of a kit and a package insert, the instructions on the insert bearing no patentable weight with regard to double patenting, 102 and 103 rejections. As such, the instant claims are anticipated by US patent 5,025,019.

Response to Applicants' arguments:

Applicants argued that there is no disclosure of instruction for administration thereof at or just before the desired sleeping time in US 5,025,019 and it is believed that there is a functional relationship between the label or package insert of a kit and the composition since the instructions are for administration of the actives at or just before the desired sleeping time".

As stated in the previous action mailed on 6/20/2008, the limitation, "administration thereof at or just before the desired sleeping time" recited on the label or package of the insert, which is an intended use of the composition, lacks a function relationship because the insert or label does not physically or chemically affect the chemical nature within the article of

manufacture. See MPEP 2111.02: Intended use recitations and other types of functional language cannot be entirely disregarded. However, in apparatus, article and composition claims, intended use must result in a **structural difference** between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In the instant case, the intended use does not result in a structural difference between the claimed invention and the prior art and the composition of the prior art can be administered "at or just before the desired sleeping time" as recited in the instant claims, thus the prior art anticipates the instant claims.

2) Claims 14, 16, and 32-33 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent Application Publication 2002/0058642 (Pub. Date: 5/16/2002).

US 2002/0058642 disclose a composition comprising glucosamine, analgesic including ibuprofen in combination with one or more other pharmaceutical active component including triprolidine for the treatment of such ailment as allergies, sleep disorder, cough, colds, and/or flu symptoms, and arthritic and joint pain (p3, [0019]). US 2002/0058642 further teaches that the pharmaceutical composition can be prepared in admixture with a pharmaceutical carrier (p3, [0020]).

The instant composition comprises at least one further active pharmaceutical agent in combination with triprolidine, therefore the composition can include more than one further active pharmaceutical agent like glucosamine. The instant invention is directed to a composition. The dose or administration limitation does not limit the composition and does not get patentable weight. The dosing and administration is reasonably interpreted as taking a portion of the

claimed composition for administration but such portioning does not limit what is actually being claimed. Also, an intended use, which is enabling an individual wake refreshed, does not have a patentable weight as stated before. With regards to the instruction, the printed matter on a label or package insert of a kit or container does not lend patentable weight as a limitation of the claimed product, composition, or article of manufacture since there is no functional relationship between the label or package insert of a kit and the product, composition, or article of manufacture of a kit or container as stated before. As such, the instant claims are anticipated by US 2002/0058642.

Response to Applicants' arguments:

Applicants argued that none of the exemplified compositions in US 2002/0058642 includes triprolidine. In addition, they argued that there is no disclosure of instruction for administration thereof at or just before the desired sleeping time in the reference and it is believed that there is a functional relationship between the label or package insert of a kit and the composition since the instructions are for administration of the actives at or just before the desired sleeping time".

Although the exemplified compositions in US 2002/0058642 do not include triprolidine, the reference lists triprolidine as a preferable example of additional pharmaceutical actives for glucosamine/analgesic formulation. When the species is clearly named, the species claims is anticipated no matter how many other species are additionally named. *Ex parte A*, 17 USPQ2d 1716 (Bd. Pat. App. & Inter. 1990). In addition, one of ordinary skill in the art would at once envisage the combination of glucosamine with triprolidine selected from the limited number of

clearly named species of additional pharmaceutical actives. As stated in the previous action mailed on 6/20/2008, the limitation, "administration thereof at or just before the desired sleeping time" recited on the label or package of the insert, which is an intended use of the composition, lacks a function relationship because the insert or label does not physically or chemically affect the chemical nature within the article of manufacture. See MPEP 2111.02: Intended use recitations and other types of functional language cannot be entirely disregarded. However, in apparatus, article and composition claims, intended use must result in a **structural difference** between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In the instant case, the intended use does not result in a structural difference between the claimed invention and the prior art and the composition of the prior art can be administered "at or just before the desired sleeping time" as recited in the instant claims, thus the prior art anticipates the instant claims.

Provisional Double Patenting Rejection

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference

claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 14, 16, and 32-33 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 48 and 57 of copending Application No. 10/448,455. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the '455 application claims and the instant claims encompass a composition comprising triprolidine or a salt or hydrate thereof in combination with at least one further active pharmaceutical agent for enabling an individual to wake refreshed since having a instruction or a dosage limitation bears no patentable weight with regard to double patenting, 102 and 103 rejections as stated above.

This is a provisional obviousness-type double patenting rejection.

Response to Applicants' arguments:

Applicant's request that the Double Patenting rejection be held in abeyance until the outcome of prosecution of the present application and that of 10/448,455 is noted. However, Applicants have not presented a terminal disclaimer and the claims of the above co-pending application remain pending, thus the rejection is properly maintained.

Conclusion

No claims are allowed.

No new ground(s) of rejection is presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BONG-SOOK BAEK whose telephone number is 571-270-5863. The examiner can normally be reached 9:00-6:00 Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian-Yong S Kwon/
Primary Examiner, Art Unit 1614
Bbs

BONG-SOOK BAEK
Examiner, Art Unit 1614